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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,739	12/01/2000	Mark A. Sheridan	255.0004	4181

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/21/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,739

Applicant(s)

SHERIDAN ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,12 and 13 is/are rejected.
- 7) ☒ Claim(s) 3,14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Application**

The Request filed on June 13, 2003 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/775,181 is granted. An action on the RCE follows.

### **Applicants' Amendment**

Applicants' amendment in Paper No. 27 filed on June 13, 2003 has been entered in full. Claims 1-3 and 12-15 are currently pending and under consideration. Further, upon Applicants' request and argument, the Examiner agrees to search and consider the amino acid subsequences SEQ ID NOS: 2 and 16-19.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Claim Rejections Under 35 U. S. C. § 102 (b)**

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (*IDS, General and Comparative Endocrinology*, 98:253-261, 1995).

Moore et al. teach a somatostatin polypeptide of preprosomatostatin II (See, e.g., Abstract and Fig. 2), which is a bioactive analog of SEQ ID NO: 15 and shares 79.7%

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sequence identity with SEQ ID NO: 15 (See attached sequence alignment). It is noted that the polypeptide comprises 27 contiguous amino acids from SEQ ID NO: 17, and 22 amino acids of SEQ ID NO: 16 with the first 3 amino acids of SEQ ID NO: 16 (SVD) missing. Otherwise, the reference would meet the limitations of claim 1, parts b and d. Nonetheless, the reference still meets the limitations of claim 1 (d).

Since the amino acid sequence taught by Moore et al. comprises SEQ ID NO: 2 (the last 14 amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16), the reference of Moore et al. also meets the limitations of claim 2.

#### **Claim Rejections Under 35 U. S. C. § 103 (a)**

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. (*IDS*, General and Comparative Endocrinology, 98:253-261, 1995), as applied to claims 1 and 2, in view of Hobart et al. (EU 46669 A1, March 3, 1982).

Moore et al. teach a somatostatin polypeptide of preprosomatostatin II (See, e.g., Abstract and Fig. 2), which is a bioactive analog of SEQ ID NO: 15, shares 79.7% sequence identity with SEQ ID NO: 15, and comprising SEQ ID NO: 2, as discussed above. Moore et al. fail to teach a fusion somatostatin polypeptide.

Hobart et al. teach a method for making a fusion protein comprising the amino acid sequence of a somatostatin or a somatostatin precursor as its C-terminal region and a bioactive moiety as its N-terminal (page 3, last but one paragraph; claim 22).

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Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce a fusion protein comprising an N-terminal somatostatin region comprising a somatostatin polypeptide taught by Moor et al. covalently linked to a C-terminal region comprising a second amino acid sequence which is a bioactive moiety with a reasonable expectation of success. One would have been motivated to do so because somatostatin polypeptides have important physiological roles in the growth of vertebrates, such as inhibition of pancreatic and gastrointestinal tract hormone secretion (See, page 253 of Moore et al.) and the fusion polypeptide can deliver a bioactive moiety to a target cell via specific binding of the somatostatin polypeptide to its receptor in the cell.

**Claim Objection**

Claims 3, 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
August 15, 2003

*Yvonne Eyler*  
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